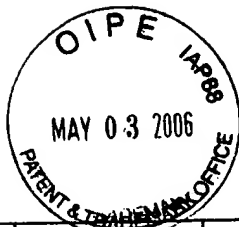


**ATTORNEY DOCKET No. 14014.0025US**  
**Application No. 07/110,791**

# **EXHIBIT 2**



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/110,791	10/21/87	KINE	14014.0025 DGP

18M2/0918  
NEEDLE & ROSENBERG, P.C. SUITE 1200  
THE CANDLER BUILDING  
127 PEACHTREE STREET, N.E.  
ATLANTA GEORGIA 30303

**RECEIVED**

SEP 23 1996

NEEDLE & ROSENBERG

MARSCO EXAMINER	
ART UNIT	PAPER NUMBER
1807	

DATE MAILED:

09/18/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

**DOCKETED**

By: ChB Date: 9-26-96

Reviewed: No dates to be docketed DGP  
Name/Date

# BOARD OF PATENT APPEALS / INTERFERENCE INITIAL MEMORANDUM

INTERFERENCES: An interference is found to exist between the following cases:

This interference involves \_\_\_\_\_ parties

PARTY <b>KING ET AL</b>	APPLICATION NO. <b>07/110,791</b>	FILING DATE <b>10/21/87</b>	PATENT NO., IF ANY _____	ISSUE DATE, IF ANY _____
If application has been patented, have maintenance fees been paid? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Maintenance fees not due yet				
**Accorded the benefit of:				
COUNTRY <b>US</b>	APPLICATION NO. <b>06/836,414</b>	FILING DATE <b>3/5/87</b>	PATENT NO., IF ANY _____	ISSUE DATE, IF ANY _____
The claim(s) of this party which correspond(s) to this count is(are): <b>PATENTED OR PATENTABLE PENDING CLAIMS</b> <b>44, 46, 47, and 60-62</b>				
UNPATENTABLE PENDING CLAIMS				
The claim(s) of this party which does(do) not correspond to this count is(are): <b>PATENTED OR PATENTABLE PENDING CLAIMS</b>				
UNPATENTABLE PENDING CLAIMS				

PARTY <b>SLAMON ET AL</b>	APPLICATION NO. <b>06/948265</b>	FILING DATE <b>12/31/86</b>	PATENT NO., IF ANY <b>4,968,603</b>	ISSUE DATE, IF ANY <b>11/6/90</b>
If application has been patented, have maintenance fees been paid? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Maintenance fees not due yet				
**Accorded the benefit of:				
COUNTRY	APPLICATION NO.	FILING DATE	PATENT NO., IF ANY	ISSUE DATE, IF ANY
The claim(s) of this party which correspond(s) to this count is(are): <b>PATENTED OR PATENTABLE PENDING CLAIMS</b> <b>1-22</b>				
UNPATENTABLE PENDING CLAIMS				
The claim(s) of this party which does(do) not correspond to this count is(are): <b>PATENTED OR PATENTABLE PENDING CLAIMS</b>				
UNPATENTABLE PENDING CLAIMS				

## Instructions

- For every patent involved in the interference, check if the maintenance fees have been paid by using the patent number with PALM screen 2970. If fees are due and they have not been paid, the interference cannot be declared since it would involve an expired patent (35 USC 135(a); 37 CFR 1.606).
- For each party, identify the patentable (or patented) and unpatentable (pending) claims which correspond to the count (37 CFR 1.601(f), (n); 1.609(b)(2)).
- For each party, identify the patentable (or patented) and unpatentable (pending) claims which do not correspond to the count (37 CFR 1.609(b)(3)).
- Forward all files including those the benefit of which is being accorded.
- Keep a copy of the Interference Initial Memorandum and any attachments for your records.

All information requested below must be attached on (a) separate typewritten sheet(s).

- On a separate sheet, set forth a single proposed interference count. If any claim of any party is exactly the same word for word as this count, please indicate the party, application or patent number, and the claim number.
- For each claim designated as corresponding to the count, provide an explanation of why each claim defines the same patentable invention as the count (37 CFR 1.609(b)(2)).
- For each claim designated as not corresponding to the count, provide an explanation of why each claim defines a separate patentable invention from the count (37 CFR 1.609(b)(3)).
- For each additional count, if any, repeat steps 2-6 and, additionally, provide an explanation why each count represents a separate patentable invention from every other count (37 CFR 1.609(b)(1)).

DATE <b>9/16/96</b>	PRIMARY EXAMINER (Signature) <i>John D. Marshall</i>	TELEPHONE NO. <b>(703) 308-3894</b>	ART UNIT <b>807</b>
DATE	GROUP DIRECTOR SIGNATURE (if required)		

\*\*The application number and filing date of each application the benefit of which is intended to be accorded must be listed. It is not sufficient to merely list the earliest application if there are intervening applications necessary for continuity.

THIS PAGE CAN BE DUPLICATED IF THERE ARE MORE THAN TWO INTERFERING PARTIES.

Revised PTO-850 Interference Initial Memorandum appears on the reverse side of this sheet. This form has been revised to include the changes made to the interference rules as set forth in 1173 OG 49, particularly the changes to 37 C.F.R. § 1.609.

### HIGHLIGHTS

#### 1. Maintenance Fees

An interference is an extremely expensive and time consuming proceeding. When a patent is to be involved in an interference, such interference can only be set up with an *unexpired* patent. 35 U.S.C. § 135 and 37 C.F.R. §§ 1.602, 1.606, and 1.607. Since the examiner has the initial responsibility for reviewing the interfering applications and patents, it falls within the responsibility of the Examining Group to insure that the patent in question is in fact unexpired. This requires checking if the proper maintenance fees have been timely paid. Until this is done, the files should not be forwarded for declaration of an interference. The revised form includes instructions on how to verify whether Maintenance Fees for a U.S. Patent have been paid.

#### 2. Explanation of why claims correspond to a count

Section 1.609(b)(2) of 37 C.F.R. requires an examiner's statement explaining why each claim designated as corresponding to a count is directed to the same patentable invention as the count. The purpose of the statement is to provide the Board and the parties involved in the interference with the benefit of the examiner's reasoning while deciding whether the interference should be declared and during consideration of preliminary motions. The reasoning set forth in 37 C.F.R. 1.601(n) must be followed consistent with Office practice for justifying rejections. This information must be typewritten on separate sheets of paper.

#### 3. Explanation of why claims do not correspond to a count

Section 1.609(b)(3) of 37 C.F.R. requires an examiner's statement explaining why each claim designated as not corresponding to *any* count is not directed to the same patentable invention as *any* count. As above, this statement would provide the Board and the parties involved in the interference with the benefit of the examiner's reasoning during consideration of preliminary motions. The reasoning set forth in 37 C.F.R. 1.601(n) must be followed consistent with Office practice for justifying allowances. This information must be typewritten on separate sheets of paper.

#### 4. Multiple Counts

In cases in which multiple counts are involved, 37 C.F.R. 1.609(b)(1) stipulates that the examiner must present reasons why each count is patentably distinct from the other counts. Once more, the reasoning set forth in 37 C.F.R. 1.601(n) must be followed consistent with Office practice for justifying allowances. If the examiner cannot justify the patentability of one count over another count, then they must be considered as directed to the same invention and, thus, only one count would be required for the inter partes proceedings. This information must be typewritten on separate sheets of paper.

If you have any questions concerning the new form or the rule changes, feel free to contact a Program and Resource Administrator at 703-308-9797.

Interference summary for 07/110,791 versus P/N 4,968,603.

Proposed phantom count: (combination of claim 44 of 07/110,791 and claim 1 of P/N 4,968,603)

A method of diagnosing or evaluating human cancer in a patient comprising: measuring the level of amplification in a tissue or tumor sample containing cells from said patient or increased expression of a MAC117 gene in a body sample from said patient, the presence of amplification or increased expression of said MAC117 gene indicating the presence of cancer or a cancer with a more malignant phenotype

OR

A method for screening patients to determine disease status, said method comprising: measuring the level of amplification or expression of the HER-2/neu gene in a sample from a patient suffering from breast or ovarian adenocarcinoma; and classifying those patients having an increased level of amplification or expression of the HER-2/neu gene relative to a reference level characteristic of normal cells as being more likely to suffer disease relapse or having a decreased chance of survival.

(Note that the Her-2/neu gene and the MAC117 gene are the same gene as summarized in P/N 4,968,603 in column 2, lines 39-43.)

All of the claims of 07/110,791 and P/N 4,968,603 correspond to the count in that they all are directed to evaluation, diagnosis, screening, or evaluation of cancer treatment as directly related procedures in that they are all based on the

analysis of the same gene regarding whether it is amplified, rearranged, or overexpressed in the tissue being tested. Such amplification, rearrangement, or overexpression being indicative of cancer diagnosis or when expressed regarding extent of gene alteration as indicative of a worsening condition of the patient whether being treated or not.

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PATENT EXAMINER  
GROUP 1600